Assembly Bill No. 58

CHAPTER 547

An act to amend Section 24177.5 of the Health and Safety Code, relating to medical experiments.

[Approved by Governor October 4, 2013. Filed with Secretary of State October 4, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 58, Wieckowski. Medical experiments: human subjects.

Existing law regulates the conduct of medical experiments on human subjects and requires informed consent prior to conducting medical experiments on human subjects. Existing law, until January 1, 2014, exempts from this requirement a medical experimental treatment that benefits a patient subject to a life-threatening emergency if specified conditions are met, including that the patient is in a life-threatening situation necessitating urgent intervention and available treatments are unproven or unsatisfactory and informed consent cannot be obtained before treatment must be administered.

This bill would continue the exemption for life-threatening emergencies indefinitely and would add conditions for the use of medical experimental treatment, including that the institutional review board has reviewed and approved the informed consent procedures and these procedures are to be used with subjects or their legally authorized representatives in situations where use of the procedures and documents is feasible and that specified additional protections of the rights and welfare of the subjects will be provided.

The people of the State of California do enact as follows:

SECTION 1. Section 24177.5 of the Health and Safety Code is amended to read:

24177.5. (a) This chapter does not apply to a medical experimental treatment that benefits a patient subject to a life-threatening emergency if all of the following conditions are met:

(1) Care is provided in accordance with the procedures and the additional protections of the rights and welfare of the patient set forth in Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code of Federal Regulations, in effect on April 1, 2012.

(2) The patient is in a life-threatening emergency necessitating urgent intervention and available treatments are unproven or unsatisfactory.

(3) The patient is unable to give informed consent as a result of the patient's medical condition.

(4) Obtaining informed consent from the patient's legally authorized representatives is not feasible before the treatment must be administered. The proposed investigational plan shall define the length of time of the potential therapeutic window based on scientific evidence, and the investigator shall commit to attempting to contact a legally authorized representative for each subject within that length of time and, if feasible, to asking the legally authorized representative contacted for consent within that length of time rather than proceeding without consent.

(5) There is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the clinical investigation.

(6) Valid scientific studies have been conducted that support the potential for the intervention to provide a direct benefit to the patient. Risks associated with the investigation shall be reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

(7) The institutional review board has reviewed and approved the informed consent procedures and these procedures are to be used with subjects or their legally authorized representatives in situations where use of the procedures and documents is feasible.

(8) Additional protections of the rights and welfare of the subjects will be provided, including, but not limited to, all of the following:

(A) Consultation, including, where appropriate, consultation carried out by the institutional review board, with representatives of the communities in which the research will be conducted and from which the subjects will be drawn.

(B) Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to the initiation of the research, of plans for the research and its risks and expected benefits.

(C) Public disclosure of sufficient information following the completion of the research to apprise the community and researchers of the study, including demographic characteristics of the research population and the results of the study.

(D) Establishment of an independent data monitoring committee to exercise oversight of the research.

(b) This section does not relieve any party of any other legal duty, including, but not limited to, the duty to act in a nonnegligent manner.

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